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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,478	02/25/2002	John L. Ricci	1065.36	4351
7590 Melvin K. Silverman Suite 500 500 Est Cypress Creek Road Fort Lauderdale, FL 33309	03/23/2007		EXAMINER BLANCO, JAVIER G	
			ART UNIT 3738	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	03/23/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/081,478	RICCI ET AL.
	Examiner	Art Unit
	Javier G. Blanco	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 December 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. Applicants' amendment of claims 21-27 in the reply filed on December 18, 2006 is acknowledged.
2. Applicants' addition of claims 28-36 in the reply filed on December 18, 2006 is acknowledged.

**Affidavit/Declaration**

3. The Declaration filed on December 18, 2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the Naiman et al. (US 5,607,607) and Curtis et al. (US 5,833,641) references.
4. The inventive entity in Naiman et al. '607 is different from the inventive entity of the present application (10/081,478) and US 6,419,491.
5. The evidence submitted is insufficient to establish proof of conception of the invention and reduction to practice of the invention prior to the effective filing date of the Naiman et al. (US 5,607,607) and Curtis et al. (US 5,833,641) references. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

***Priority***

6. The instant application (10/081,478; filed February 25, 2002):

- (i) Is a continuation-in-part of application 09/500,038 (filed February 8, 2000, now US 6,419,491),
- (ii) Which is continuation-in-part of application 08/996,244 (filed December 22, 1997, now abandoned),
- (iii) Which is continuation of application 08/639,712 (filed April 29, 1996, now abandoned),
- (iv) Which is continuation of application 08/390,805 (filed February 15, 1995, now abandoned),
- (v) Which is continuation of application 08/146,790 (filed November 2, 1993, now abandoned).

7. Upon reviewing application 08/146,790 (filed during the Response/Amendment of December 18, 2006), the Examiner was not able to find support for: (i) "*substantially planar*"; (ii) "*proportioned to*"; and (iii) "*promoting bone tissue growth*" in said application. Since not every element disclosed in independent claims 21, 28, and 29 is disclosed in application 08/146,790, therefore the effective filing date for claims 21, 28, and 29 is assumed not to be November 2, 1993.

8. It is noted that the present Application is a continuation-in-part of US 6,419,491 B1. The subject matter of claims 22-27 and newly added dependent claims 30-36 was not disclosed/described in US 6,419,491 B1 (or application 08/146,790). Therefore, the effective filing date for claims 22-27 and newly added dependent claims 30-36 is considered to be

February 25, 2002. The elements of the Markush claims 25 and 34 were not disclosed in US 6,419,491 B1 (or application 08/146,790).

9. The Applicants have made a claim of priority under 35 U.S.C. § 120. However, the requirements of 35 U.S.C. § 120 must be met before claims in an application are entitled to the benefit of the filing date of any earlier-filed application to which the Applicants have made a claim of priority under 35 U.S.C. § 120. In the instant application, the record must show that the 09/500,038, 08/996,244, 08/639,712, 08/390,805, and 08/146,790 applications contain a disclosure which complies with 35 U.S.C. § 112, first paragraph, for each claim in the subsequently filed 10/081,478 application. *Studiengesellsehafi Kohle m.b.H.v. Shell Oil Co.*, 112 F.3d 1561, 1564-65, 42 USPQ2d 1674, 1677-78 (Fed. Cir. 1997).

The Applicants must analyze each application in the train of earlier-filed applications to see if they contain a disclosure which complies with 35 U.S.C. § 112, first paragraph, for each claim in the subsequently filed 10/081,478 application and make the necessary findings showing that the claims are entitled to the benefit under 35 U.S.C. § 120 of the filing dates of at least the 09/500,038 and 08/996,244 applications.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 21 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 21 and 28 of the application and (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569 lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569 is in effect a “species” of the “generic” invention of claims 21 and 28. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 21 and 28 are anticipated by (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569, it is not

patentably distinct from (i) claims 1, 2, 18, and 22 of U.S. Patent No. 6,419,491, and (ii) claims 1, 8, and 9 of U.S. Patent No. 6,454,569.

12. Claims 21 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Application No. 09/784,284. Although the conflicting claims are not identical, they are not patentably distinct from each other because these applications claim an implantable article comprising microtexturized surfaces comprising grooves and ridges having a width and height of about 2 to about 10 micrometers (microns). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Claim Objections*

13. Claim 28 is objected to because of the following informalities: please substitute “comprising” (see line 1) with --comprises a--. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 102*

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 21, 28, and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Frey (US 3,848,273 A).

Referring to Figures 1, 4, and 5, Frey discloses a substrate comprising a substantially planar (the term "planar" is generally defined as "*of, relating to, or situated in a plane*"; "*lying in a plane*") structure having a first micro-textured surface (e.g., one face, side, or end of textured surfaces 6, 7, 17) and an opposing surface (e.g., an opposite/opposing face, side, or end of textured surfaces 6, 7, 17), wherein said first micro-textured surface and said opposing surface comprising grooves and ridges (Figures 4 and 5) having a width and height of about 10 microns (notice that "*of about 2 to about 10 microns*" and "*about 8 to about 12 microns*" overlap in range; i.e., 8-10 microns). See column 1, lines 41-53; column 3, lines 1-5, lines 20-25, and lines 36-39.

**Note:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

16. Claims 21-23 and 28-32 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by von Recum et al. (US 5,011,494 A; having an effective filing date of September 16, 1988).

Referring to Figures 2, 4, 5, 6A, 6B, 9-11, and 13, von Recum et al. disclose a substrate comprising a substantially planar (e.g., "sheet"; see column 14, lines 54-56) structure having a first micro-textured surface (e.g., one face, side, or end of surface layer 52) and an opposing surface (e.g., an opposite/opposing face, side, or end of surface layer 52), wherein said first micro-textured surface comprising grooves and ridges (Figures 2, 4, and 5: recesses/grooves 54/60 and projections/ridges 56, 84) having a width and height of about 2 to about 10 microns and said opposing surface comprising grooves and ridges (Figures 2, 4, and 5: recesses/grooves 54/60 and projections/ridges 56, 84) having a width and height of about 8 to about 12 microns. It should be noted that "*of about 2 to about 10 microns*" and "*about 8 to about 12 microns*" overlap in range (i.e., 8-10 microns). Von Recum et al. disclose depths ranging from 1 micron to 150 microns (see column 11, lines 11-15), and recess/groove/pore diameters ranging from 0.2 microns to 10 microns (see column 14, lines 25-27). The flexible sheet may have a thickness of between about 200 and about 500 microns (see Table I).

**Note:** The term "planar" is generally defined as "*of, relating to, or situated in a plane*"; "*lying in a plane*".

**Note:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

17. Claims 21, 28, and 29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892).

Referring to Figures 4A-4H, 5A-5F, 6A-6E, and 7-9, Naiman et al. disclose an implantable article (**Figure 7**: implant 46; **Figure 8**: hip prosthesis 54; **Figure 9**: dental implant 55) comprising micro-textured upper (Figure 7: grooves 44 and ridges 45 on upper surface; Figure 8: zone II; Figure 9: zone 61) and lower (Figure 7: grooves 48 and ridges inside cavity 47; Figure 8: zone I; Figure 9: zone 62) surfaces; said upper surface comprising grooves and ridges having a width and a height of about 2 to about 10 microns (see columns 9, 10, and 16), *proportioned to* (emphasis added to intended use) a cell morphology of soft tissue cells (see columns 11-13); and said lower surface comprising grooves and ridges having a width and a height of about 8 to about 25 microns (see columns 9, 10, and 16), *proportioned to* (emphasis added to intended use) a cell morphology of bone tissue cells (see columns 11-13); said article being substantially planar and biocompatible. Nayman et al.'s invention is applicable to various implants/prostheses or substrates

a. It should be noted that the claimed range of the width and height (depth) of the "grooves" and "ridges" of the upper surface overlaps the claimed range of the width and height (depth) of the "grooves" and "ridges" of the lower surface.

b. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no

significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 22-27 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naiman et al. (US 5,607,607 A; previously cited by the Examiner in PTO-892) in view of Curtis et al. (US 5,833,641; cited in Applicants' IDS).

Naiman et al. disclose the invention as claimed in claim 1. Although Naiman et al. disclose/suggest their invention as applicable to various implants/prostheses and substrates (e.g., sheets), they did not particularly disclose their article as bioabsorbable article having a thickness of between about 200 and about 500 microns, and a weight in a range of one to five grams/cm<sup>2</sup>. However, this is already known in the art.

Curtis et al. disclose a cell growth orienting means either integrally formed or provided on the surface of implants/prostheses (see column 2, lines 31-46), or as a bioabsorbable/biodegradable membrane/sheet/substrate (see Figure 1; column 2, lines 31-46; column 3, line 55 to column 4, line 2) wherein the biodegradable membrane/sheet/substrate defines a width of between about 200 microns and about 500 microns and a weight in a range of one to five grams/cm<sup>2</sup> (see column 3, lines 49-54; see column 4; see entire document) in order to provide a flexible nature to

the membrane/sheet/substrate, allowing it to be inserted into wounds or wrapped around prostheses (see columns 2-4). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an implantable substrate having cell growth orienting means, a thickness of between about 200 and about 500 microns, and a weight in a range of one to five grams/cm<sup>2</sup>, as taught by Curtis et al., with the implantable article (e.g., substrate) of Naiman et al., in order to provide a flexible nature to the membrane/sheet/substrate, allowing it to be inserted into wounds or wrapped around prostheses. Also, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

March 14, 2007



David H. Willes  
Primary Examiner